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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

George E. Barringer, Jr., Stephen C. Phillips and Mark J. Phillips

Application No.:

10/600,177

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For:

METHOD AND APPARATUS FOR OPERATING AN AUTOMATED CAPILLARY ELECTROPHORESIS SYSTEM (AS AMENDED)

CERTIFICATE OF MAILING OR TRANSMISSION

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DECLARATION OF GEORGE E. BARRINGER, JR., UNDER 37 C.F.R. § 1.132

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

- 1. My name is George E. Barringer, Jr., and I am over eighteen years of age and competent to testify.
- My address is 85 Swanson Road, Suite 110, Boxborough, MA 01719. I am the Founder, Executive Vice President, and Chief Science Officer of Groton Biosystems.
- 1 have reviewed and understand the Office Action dated January 27, 2009 and the subject patent application by Virtanen (6,402,919).
- This Declaration is directed to the Office's anticipation rejection in the Office Action under 35 U.S.C. \$102(b).

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5. 1 am a chemist with a Ph.D. in Analytical Chemistry from Lehigh University. 1 was a National Institute of Health (NIH) Fellow of the University of Pennsylvania Medical School and a faculty member at Lehigh University, and 1 am currently an adjunct professor with the Lehigh Educational Satellite Network.

- 6. I have over 20 years experience as a biochemistry professional and biotechnology entrepreneur. I began my industrial career at American Hoechst, Inc. as Analytical Services Director. I founded Groton Technology, Inc. in 1984, specializing in the design and manufacture of sophisticated detection systems for High Performance Liquid Chromatography (HPLC), Capillary Electro Chromatography (CEC), and Flow Injection Analysis (FIA) applications. These are all forms of chemical separation intended to separate and detect individual chemical compounds from complex mixtures.
- In 2003, I founded Groton Biosystems, Inc. ("Groton Biosystems") to focus on the
 specialized needs of biotechnology professionals
 automated systems for chemical process analysis. The company's main focus is
 development of automated systems for online, at line, and near line analysis of upstream
 and downstream biotechnology processes.
- I am a person of ordinary skill in the art with respect to capillary electrophoresis systems, and it is my belief that a person of ordinary skill in the art to which the present invention is directed is a chemist.
- 9. My co-inventors in the patent application, Stephen C. Phillips and Mark J. Phillips, are programmers without chemistry training whose inventive contributions relate to the automation aspects of the present invention as claimed. Their skill in computer programming and computer hardware exceeds that of myself or other persons of ordinary skill in the art of capillary electrophoresis systems.

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10. I understand the subject matter of the Virtanen patent (6,402,919), which is related to a capillary electrophoresis apparatus. Virtanen states that his "entire apparatus can be controlled by means of a micro-processor" at column 3, lines 36-37.

- 11. A person of ordinary skill in the art of electrophoresis, i.e., a chemist like myself, would not be able to implement a sophisticated system like the presently claimed invention (e.g., Claim 27) on the basis of the Virtanen patent alone. The present invention as claimed goes far beyond mere control by a microprocessor and also beyond modifiable parameters as in Virtanen. For example, the present invention as claimed in Claim 27 includes "a controller operatively coupled to [an] input valve and including executable instructions to convert and execute operational input to control the valve." Converting and executing operational input goes beyond the skill of a person of ordinary skill in the art of capillary electrophoresis and goes beyond the teachings and suggestions of Virtanen.
- 12. A person of ordinary skill in the art, who would be a chemist skilled in the art of electrophoresis, like me, would seek a turnkey solution such that knowledge of computer programming would not be necessary to operate a capillary electrophoresis system. An end user would typically want to press a button or perform other simple steps to operate a chemical process without relying on discrete step-by-step control of valves and equipment. Such an end user would not want (or know how) to perform intricate programming to accomplish electrophoretic processing tasks.
- 13. Previously, between 1994 and 2006, my company worked with Perkin Elmer, Inc., which is a company marketing High Performance Liquid Chromatography (HPLC) for life science applications. Groton provided an automated HPLC detector processing system for spectral detection and quantitation (determining or measuring the quantity of a substance). That system was typical for the field in that it was a turnkey solution with all control and command instructions for the detector imbedded in a compiled operating system inaccessible to the user.

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- 14. The present invention as claimed goes beyond the turnkey-style automation we developed for Perkin Elmer. The present invention as claimed involves a novel technique that uses operational input that is converted and executed to control valves and processes for electrophoretic processing to enable a chemist to perform and adapt various processing tasks flexibly as needed. An example of the operational input can be in the form of a set of English phrases, e.g., "open_valve SV1026," where SV1026 is a valve at a known position within the capillary electrophoresis system under software control, or "wait_for_syringes." By enabling the end user to communicate with the system in pseudo language, the present invention as claimed adds a level of functionality and usability that is not found in conventional turnkey systems and that is not rendered obvious by Virtanen. In other words, the intermediate level processing of operational input ("to convert and execute operational input to control [a] valve for providing a sample of the liquid source to the capillary electrophoresis column" (emphasis added)), as recited in independent Claim 27 and similarly in independent Claims 39 and 52, is not inherent or obvious in the context of conventional capillary electrophoresis systems and/or Virtanen.
- 15. I further declare that all statements made in this Declaration of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements of the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

George E. Barringer, Jr.

MAY 27, 2009